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JC07 Rec'd PCT/PTO 19 MAR 2002

FORM PTO-1390 (REV 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

# TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

| ATTORNEY'S DOCKET NUMBER | |
|---|---|
| 0104-0385P | |
| U.S. APPLICATION NO. (If known, see 37 CFR 1.5) | 10/088555 NEW |

| INTERNATIONAL APPLICATION NO. | INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED |
|---|---|---|
| PCT/SE00/01871 | September 28, 2000 | October 6, 1999 |

**TITLE OF INVENTION**

RECTAL INSERTION DEVICE

**APPLICANT(S) FOR DO/EO/US**

NESTENBORG, Daniel

**Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:**

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau). (WO 01/24743)
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is transmitted herewith.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11. to 20. below concern document(s) or information included:**

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form PTO-1449(s), and International Search Report (PCT/ISA/210) with 5 cited document(s).
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:
    1.) International Preliminary Examination Report (PCT/IPEA/409)
    2.) Two (2) Sheets of Formal Drawings

10/088555 JC05 Rec'd PCT/PTO 19 MAR 2002

| U.S. APPLICATION NO (if known, see 37 CFR 1.5) | INTERNATIONAL APPLICATION NO | ATTORNEY'S DOCKET NUMBER |
|---|---|---|
| NEW 10/088555 | PCT/SE00/01871 | 0104-0385P |

21. ☒ The following fees are submitted:

| | | CALCULATIONS PTO USE ONLY | |
|---|---|---|---|
| **BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5):** Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. . . . . | **$1,040.00** | | |
| International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO . . . . . | **$890.00** | | |
| International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO. . . . . | **$740.00** | | |
| International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) . . . . . | **$710.00** | | |
| International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4). . . . . | **$100.00** | | |
| **ENTER APPROPRIATE BASIC FEE AMOUNT =** | | **$ 1,040.00** | |
| Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)). | | **$ 130.00** | |

| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
|---|---|---|---|---|---|
| Total Claims | 38 - 20 = | 18 | X **$18.00** | **$ 324.00** | |
| Independent Claims | 3 - 3 = | 0 | X **$84.00** | **$ 0.00** | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | Yes | | + **$280.00** | **$ 280.00** | |
| **TOTAL OF ABOVE CALCULATIONS =** | | | | **$ 1,774.00** | |
| ☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. | | | | **$ 0.00** | |
| **SUBTOTAL =** | | | | **$ 1,774.00** | |
| Processing fee of **$130.00** for furnishing the English translation later than ☐20 ☐30 months from the earliest claimed priority date (37 CFR 1.492(f)). + | | | | **$ 0.00** | |
| **TOTAL NATIONAL FEE =** | | | | **$ 1,774.00** | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property + | | | | **$ 0.00** | |
| **TOTAL FEES ENCLOSED =** | | | | **$ 1,774.00** | |
| | | | | **Amount to be: refunded** | **$** |
| | | | | **charged** | **$** |

a. ☒ A check in the amount of $ **1,774.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

Send all correspondence to:
**Birch, Stewart, Kolasch & Birch, LLP or Customer No. 2292**
**P.O. Box 747**
**Falls Church, VA 22040-0747**
**(703) 205-8000**

**Date: March 19, 2002**

By James T. Eller, Jr. #39,538
Joe McKinney Muncy #32,334

/rem

PATENT
0104-0385P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: NESTENBORG, Daniel

Int'l. Appl. No.: PCT/SE00/01871

Appl. No.: New Group:

Filed: March 19, 2002 Examiner:

For: RECTAL INSERTION DEVICE

PRELIMINARY AMENDMENT

**BOX PATENT APPLICATION**
Assistant Commissioner for Patents
Washington, DC 20231

March 19, 2002

Sir:

The following Preliminary Amendments and Remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE SPECIFICATION:

Please amend the specification as follows:

Before line 1, insert --This application is the national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/SE00/01871 which has an International filing date of September 28, 2000, which designated the United States of America.--

Docket No. 0104-0385P

IN THE CLAIMS:

Please amend the claims as follows:

6. (Amended) A rectal insertion device as claimed in claim 1, wherein the forward end of the rearward section (3) has a transverse dimension greater than the transverse dimension of the forward section (8), the forward section (8) extending forwardly from the forward end of the rearward section (3).

7. (Amended) A rectal insertion device as claimed in claim 1, wherein the forward section (8) and rearward section (3) are co-axially arranged.

8. (Amended) A rectal insertion device as claimed in claim 1, wherein the forward section (8) is arranged parallel but radially displaced relative to the rearward section (3).

12. (Amended) A rectal insertion device as claimed in claim 1, wherein the rearward section (3) of the device comprises a tubular element (3), preferably having an open-ended axial lumen.

18. (Amended) A rectal insertion device as claimed in claim 1, wherein the rearward section (3) comprises a gripping portion (15) for manoeuvring the device.

19. (Amended) A rectal insertion device as claimed in claim 1, wherein the forward section (8) is more flexible than the rearward section (3).

20. (Amended) A rectal insertion device intended for adults as claimed in claim 1, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is at least 30 mm, and preferably in the range 40-50 mm, and most preferably around 45 mm.

21. (Amended) A rectal insertion device intended for infants as claimed in claim 1, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is in the range of about 15-35 mm, and preferably in the range 20-30, and most preferably around 25, mm.

22. (Amended) A rectal insertion device as claimed in claim 1, wherein the device further comprises means for collecting faeces discharged into at least one, and preferably both, of the first and second forward openings.

25. (Amended) A rectal insertion device as claimed in claim 1, wherein the forward section (8) presents a transversely enlarged forward end portion (12).

26. (Amended) A rectal insertion device as claimed in claim 1, wherein the first passageway (9) in tapering towards the forward end of the forward section (8), making the forward opening the narrowest part of the first passageway (9).

27. (Amended) A rectal insertion device as claimed in claim 1, wherein the rearward section (3) is at least slightly tapering towards a mid-section.

Docket No. 0104-0385P

REMARKS

The specification has been amended to provide a cross-reference to the previously filed International Application.

The claims have been amended to remove improper multiple dependencies.

Entry of the above amendments is earnestly solicited. An early and favorable first action on the merits is earnestly solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By James T. Eller, Jr. #39,538
Joe McKinney Muncy, #32,334

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KM/rem
0104-0385P

Attachment: VERSION WITH MARKINGS TO SHOW CHANGES MADE

(Rev. 02/21/02)

Docket No. 0104-0385P

VERSION WITH MARKINGS TO SHOW CHANGES MADE

The specification has been amended to provide a cross-reference to the previously filed International Application.

IN THE CLAIMS:

The claims have been amended as follows:

6. (Amended) A rectal insertion device as claimed in [any one of claims 1 to 5] claim 1, wherein the forward end of the rearward section (3) has a transverse dimension greater than the transverse dimension of the forward section (8), the forward section (8) extending forwardly from the forward end of the rearward section (3).

7. (Amended) A rectal insertion device as claimed in [any one of claims 1 to 6] claim 1, wherein the forward section (8) and rearward section (3) are co-axially arranged.

8. (Amended) A rectal insertion device as claimed in [any one of claims 1 to 6] claim 1, wherein the forward section (8) is arranged parallel but radially displaced relative to the rearward section (3).

12. (Amended) A rectal insertion device as claimed in [any one of claims 1 to 11] claim 1, wherein the rearward section (3)

of the device comprises a tubular element (3), preferably having an open-ended axial lumen.

18. (Amended) A rectal insertion device as claimed in [any one of the preceding claims] claim 1, wherein the rearward section (3) comprises a gripping portion (15) for manoeuvring the device.

19. (Amended) A rectal insertion device as claimed in [any one of the preceding claims] claim 1, wherein the forward section (8) is more flexible than the rearward section (3).

20. (Amended) A rectal insertion device intended for adults as claimed in [any one of the preceding claims] claim 1, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is at least 30 mm, and preferably in the range 40-50 mm, and most preferably around 45 mm.

21. (Amended) A rectal insertion device intended for infants as claimed in [any one of claims 1 to 19] claim 1, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is in the range of about 15-35 mm, and preferably in the range 20-30, and most preferably around 25, mm.

22. (Amended) A rectal insertion device as claimed in [any one of the preceding claims] claim 1, wherein the device further comprises means for collecting faeces discharged into at least one, and preferably both, of the first and second forward openings.

25. (Amended) A rectal insertion device as claimed in [any one of the preceding claims] claim 1, wherein the forward section (8) presents a transversely enlarged forward end portion (12).

26. (Amended) A rectal insertion device as claimed in [any one of the preceding claims] claim 1, wherein the first passageway (9) in tapering towards the forward end of the forward section (8), making the forward opening the narrowest part of the first passageway (9).

27. (Amended) A rectal insertion device as claimed in [any one of the preceding claims] claim 1, wherein the rearward section (3) is at least slightly tapering towards a mid-section.

# RECTAL INSERTION DEVICE

## Field of the Invention

The present invention relates to a rectal insertion device for the treatment of disorders of the digestive tract of a human or animal patient, said device comprising a forward section which in an operative position of the device is disposed in the anal canal of the patient and a first passageway which extends rearwardly in the device from a first forward opening in the forward section. The invention further relates to a method for treatment of disorders of the digestive tract of a human or animal patient.

Disorders of the digestive tract which may be treated with rectal insertion devices of the type defined are colic, including infantile colic, haemorrhoids, constipation, gas and piles.

## Background and summary of the Invention

WO 99/30652 by the same applicant discloses a rectal insertion device of the above-mentioned type, wherein the first passageway is provided to channel faeces and gastrointestinal gases released on insertion of the forward section into the anal canal into a collection bag. A drawback of this known device is that some of the released faeces, however, may be ejected over the outer surface of the forward section instead of through the first passageway and thus not be collected in the bag. This also renders the device difficult to use efficiently.

Many of the known devices for treating disorders of the digestive tract are also difficult and expensive to produce. Further, they could also be dangerous to use, since a to deep insertion into the anal canal could result in severe injuries to the intestine. This risk is especially high when treating infants.

The aim of the present invention is to provide a rectal insertion device of the above-mentioned type which alleviates at least some of the drawbacks of the prior art devices.

According to a first aspect of the present invention there is provided a rectal insertion device of the above-mentioned type in which there is provided a rearward section having a forward end which in the operative position is disposed extra-corporeally and a second passageway which extends rearwardly in the device from a second forward opening in the forward end of the rearward section. The second passageway acts to catch faeces discharged from the anal canal not caught in the first passageway.

According to a second aspect of the invention there is provided a rectal insertion device of the above-mentioned type in which there is provided a rearward section having a forward end presenting a second forward opening intended to be extra-corporeally in use, said second forward opening being arranged rearwardly from the first forward opening. The rearward section preferably comprises a rearwardly extending, second passageway being connected to the second opening.

The device according to the invention is easy to use and produce. Further, it comprises means for collecting the released faeces ejected over the outer surface of the forward section instead of through the first passageway.

In an embodiment of the invention the forward end of the rearward section abuts with the anus of the patient in an operative position of the device. Further it is preferred that the forward end of the rearward section has a transverse dimension greater than the transverse dimension of the forward section and the forward section extends forwardly from the forward end of the rearward section. Hereby, the depth of insertion could be precisely controlled, enabling the sphincter muscles to be stimulated if need be and gastrointestinal gases and

faeces to be discharged. The abutment also sees to that a too deep insertion of the forward section into the anal canal is avoided. Hereby, the device could be used without the risk of causing any harmful injuries to the user.

In an embodiment of the invention the forward section and rearward sections are co-axially arranged. It is also preferred that second forward opening is an annulus formed around the forward section. Hereby, the device need not have a specific rotational position in use, which makes the device self-explanatory and easier to use.

In an embodiment of the invention the first passageway communicates with the second passageway. Hereby, discharged faeces and gases will be brought together, and could thereafter emanate from the same output opening, making it easier to take care of.

In an embodiment of the invention the second passageway has a rearward opening in the rearward section.

In an embodiment of the invention the rearward section of the device comprises a tube element having an open-ended axial lumen.

In an embodiment of the invention the device comprises an elongate shaft having a forward portion which presents the forward section of the device and a rearward portion which extends rearwardly from the forward portion into the lumen of the tube element and through which the first passageway extends

In an embodiment of the invention the first passageway has a rearward opening in the rearward portion of the elongate shaft.

In an embodiment of the invention the rearward portion of the elongate shaft is spaced from, and attached to, the wall of the lumen through one or more ribs.

In an embodiment of the invention the forward section is made more flexible than the rearward section in order to form a non-harmful and convenient insertion section, while the more rigid rearward section may form a convenient gripping section.

The invention also relates to a method for treating disorders of the digestive tract of a human or animal patient, comprising the step of at least one time inserting a forward section of a device into the anal canal of the patient, said forward section comprising a first passageway which extends rearwardly in the device from a first forward opening in the forward section characterised in that the device is inserted into the anal canal into a position where a rearward section of the device abuts the anus with a forward end, said rearward section comprising a second passageway which extends rearwardly in the device from a second forward opening in the forward end of the rearward section.

Other benefits and advantageous features of the invention will be apparent from the following description and claims.

An exemplary embodiment of the invention will now be described with reference to the accompanying Figures of drawings.

Brief Description of the Drawings

Figure 1 is a side view of a rectal insertion device in accordance with a first embodiment of the invention.

Figure 2a is a cross-sectional side view of the rectal insertion device of Figure 1.

Figure 2b is an elevated view of the rectal insertion device in Figure 1.

Figure 3 is a perspective view of the rectal insertion device of Figure 1.

Figure 4 is a cross-sectional side view of a rectal insertion device according to a second embodiment of the invention.

Figure 5 is an elevated view of the rectal insertion device of Figure 4.

Figure 6 is an elevated view of a rectal insertion device according to a third embodiment of the invention.

Figure 7 is an elevated view of a rectal insertion device according to a fourth embodiment of the invention.

Description of preferred embodiments

In the Figures 1-3 of drawings there is shown a rectal insertion device 1 for treating disorders of the digestive tract of a human patient such as colic in accordance with a first embodiment of the invention. In the Figures 4-7 alternative embodiments are illustrated. However, someone skilled in the art would appreciate that the features of the different embodiments may be combined in different ways, and when nothing else is stated different aspects of certain features are regarded as mutually exchangeable.

The device is preferably injection moulded from a polyether block amide, such as Pebax™ (Elf Atochem).

The device 1 has a body 3,5 comprising a rearward section comprising a tube element 3 having a second passageway, preferably comprising an open-ended axial lumen 4, and an elongate shaft 5 which is mounted in the lumen 4, preferably co-axially. In a preferred embodiment the shaft is connected to the tube element through rib elements 6 so as to define an annulus 7 between the elongate shaft 5 and the lumen wall.

In the illustrated embodiments of the invention, the lumen 4 of the tube 3 ends axially in the rearward end. However, it is also conceivable to have a rearward opening debouching radially, or at least partly in a radial direction. To this end, one or several lateral openings could be arranged on the walls of the rearward section, ahead of a preferably sealed rearward end. It is also conceivable to let the tube be curved, in which case the rearward opening debouches axially, but not

rearwardly. By providing an output opening for discharged faeces and gases not debouching rearwardly, it is avoided that discharge products are ejected onto the person manoeuvring the device.

The tube element is preferably substantially circular in cross-section, as is illustrated in the embodiments according to Figure 1-6. However, other shapes are also conceivable, e.g. oval, such as elliptic or eye-shaped, as is illustrated by the embodiment according to Figure 7. Such a shape makes the device easier to bring into abutment with the anus of the patient.

In Figures 1-3 the connection between the shaft 5 and the tube element 3 comprises two axially elongated rib elements 6. However, it is also possible to use one single rib element instead, or to use three or more rib elements, as is the case in the embodiment illustrated in Figures 4 and 5. Other alternative ways of obtaining such a connection are also possible. For example, the shaft 5 may be radially displaced relative to the tube element 3, whereby it could be directly connected to the inner wall of the tube element, as illustrated in Figure 6. Further, the ribs need not be axially elongated, but could instead be arranged axially displaced.

As can be seen, the elongate shaft 5 is divided into a rearward portion which is disposed inside the lumen 4 of the tube element 3 and a forward portion 8 which protrudes from the lumen 4. The elongate shaft 5 comprises a first passageway, in this embodiment a channel 9, which extends axially therethrough from a forward opening 11 in a forward end 12 of the shaft 5 to a rearward opening 13 in a rearward end of the shaft 5. Hereby, the first passageway 8 in the forward section 5 communicates with the second passageway 4 in the rearward section 3. However, other ways of obtaining such a communication are possible. The first passageway, instead of or in addition to having a rearward opening debouching

axially inside the second passageway, could have a lateral opening arranged inside the second passageway ahead of the rearward end, and hence debouching radially, or at least partly in a radial direction.

The forward portion 8 of the elongate shaft 5 is adapted for insertion into the anal canal of the patient, as will hereinafter be described. To this end, the forward portion of the shaft 5 is preferably provided with a coating which exhibits a reduced friction in use. Most preferably a coating which exhibits a reduced friction when wetted is used, e.g. the hydrophilic coating disclosed in EP-0 093 093 and EP-0 217 771 by the same applicant.

Further, it is preferred that the forward end 12 of the shaft 5 is enlarged. Hereby, a more efficient stimulation of the sphincter muscle is obtained when the forward section is introduced into the anal canal of the patient. The enlarged forward end preferably has a length in the range of 3-8 mm, and most preferably around 5 mm. These lengths are especially suitable when the device is intended for infants. Fur adults a suitable length could be in the range 12-20 mm, and preferably around 15 mm. Still further, it is preferred that the enlarged end constitutes a smooth transition to the shaft 5, and further presents a rounded forward end, in order to avoid discomfort for the user, and alleviate the risk of causing any harmful injuries.

Further, it is preferred that the first passageway is tapering towards the forward end of the forward section in the vicinity of the forward opening, making the forward opening the narrowest part of the first passageway. This contributes in alleviating the risk of causing injuries to the patient. Further, the risk of faeces clogging and blocking the passageway is diminished.

To this end, it is also advantageous to let the whole, or at least a substantial part of the first

passageway be slightly tapering in the length direction towards the front end. Such an embodiment is illustrated in the Figures 4 and5 in the drawings. Preferably the tapering is more accentuated adjacent to the forward opening, and less accentuated in the rest of the passageway. The whole or part of the external surface of the forward portion of the forward section may also be tapering towards the forward end.

Arranged on a mid-section of the outer surface of the tube element 3 is preferably a series of circumferential ribs 15 to assist an operator in gripping the device 1. To this end, it is also advantageous to let the rearward section be at least slightly tapering towards the mid-section.

In use of the device 1, the operator inserts the enlarged forward end 12 of the elongate shaft 5 into the anal canal of the patient until the tube element 3 abuts the anus. This is the operative position of the device 1. The abutment of the tube element 3 with the anus allows the length of the forward portion 8 of the elongate shaft 5 to be correct for the patient being treated, that is, so that the enlarged forward end 12 of the shaft 5 is positioned just past the external sphincter muscles at the entry point of the anal canal thereby enabling the sphincter muscles to be stimulated if need be and gastrointestinal gases and faeces to be discharged. With this in mind, the length of the forward portion 8 of the shaft 5, i.e. the length of the part protruding from the forward end of the rearward section, should for adults be at least 30 mm, and preferably in the range 40-50 mm, and most preferably around 45 mm. The same length for infants should be in the range of about 15-35 mm, and preferably in the range 20-30, and most preferably around 25 mm. The abutment also sees to that a too deep insertion of the forward section into the anal canal is avoided. Hereby, the device could be used without the risk of causing any harmful injuries to the user.

In an alternative embodiment (not shown) the length of the forward portion may be variable. Hereby, the length of the protruding part of the device could be adjusted to suit the intended user. For example this may be obtained by arranging the elongated shaft axially displaceably relative the rearward section. Alternatively, the rearward section may be extendable, making the forward end of the rearward section displaceable relative to the forward section.

It is also preferred that the forward section, or the elongate shaft 5, is more flexible than the rearward section, or the tube element 3. Hereby, the rearward section provides a good grip at the same time as a preferably pliable and non-harmful forward section for insertion into the anal canal is provided. This difference in flexibility could be obtained by suitable choice of dimensions and/or material thickness of the parts. However, it could also be obtained by using different materials in different parts of the device.

Once the device 1 is located in the operative position, the annulus 7 between the elongate shaft 5 and wall of the lumen 4 of the tube element 3 acts to channel into the lumen 4 of the tube element 3 faeces not discharged into the lumen 4 via the channel 9 in the elongate shaft 5. Further, the device preferably comprises means for collecting discharged faeces or gases. For example, a bag (not shown) secured to the tube element 3 as in WO99/30652 *supra* could be arranged to collect the faeces and gases discharged into the lumen 4 through the channel 9 and annulus 7. Alternately, the tube element 3 could have a sealed rear end so that the tube element 3 acts as a container for the faeces and gases. It is also conceivable to connect the discharge output to some type of per se known suction or evacuation device.

It will be understood that the invention has been illustrated by an exemplary embodiment and that the

invention can be varied in many ways within the ambit of the appended claims. For instance, the rectal insertion device can be made from many other plastic materials besides Pebax™. It will further be understood that the inclusion in the claims of reference numerals from the Figures of drawings is for illustration and not to be construed as having a limiting effect on the claims.

CLAIMS

1. A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient comprising a forward section (8) which in an operative position of the device is disposed in the anal canal of the patient and a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section characterised in that the device further comprises a rearward section (3) having a forward end which in the operative position is disposed extra-corporeally and a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section.

2. A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient, said device comprising a forward section (8) which is intended to be inserted into the anal canal of the patient and a first passageway (9) which extends in the device from a first forward opening (11) in the forward section characterised in that it further comprises a rearward section (3), having a forward end presenting a second forward opening (7) intended to be extra-corporeally in use, said second forward opening (7) being arranged rearwardly from the first forward opening (11).

3. A rectal insertion device as claimed in claim 2, wherein the rearward section (3) comprises a, preferably rearwardly extending, second passageway (4) being connected to the second opening (7).

4. A rectal insertion device as claimed in claim 1, 2 or 3, wherein in an operative position of the device the forward end of the rearward section (3) abuts with the anus of the patient.

5. A rectal insertion device as claimed in claim 1 or 3, wherein the first and second passageways (9, 4) are substantially co-axially arranged.

6. A rectal insertion device as claimed in any one of claims 1 to 5, wherein the forward end of the rearward section (3) has a transverse dimension greater than the transverse dimension of the forward section (8), the forward section (8) extending forwardly from the forward end of the rearward section (3).

7. A rectal insertion device as claimed in any one of claims 1 to 6, wherein the forward section (8) and rearward section (3) are co-axially arranged.

8. A rectal insertion device as claimed in any one of claims 1 to 6, wherein the forward section (8) is arranged parallel but radially displaced relative to the rearward section (3).

9. A rectal insertion device as claimed in claim 6, 7 or 8, wherein the second forward opening (7) is in the form of an annular opening formed around the forward section (8).

10. A rectal insertion device as claimed in claim 1 or 3, wherein the first passageway (9) communicates with the second passageway (4).

11. A rectal insertion device as claimed in claim 10, wherein the first passageway (9) has a rearward opening debouching inside the second passageway (4).

12. A rectal insertion device as claimed in any one of claims 1 to 11, wherein the rearward section (3) of the device comprises a tubular element (3), preferably having an open-ended axial lumen.

13. A rectal insertion device as claimed in claim 12, wherein the device comprises an elongate shaft (5) having a forward portion (8) which presents the forward section of the device and a rearward portion which extends rearwardly from the forward portion into the tubular element (3).

14. A rectal insertion device as claimed in claim 13, wherein the first passageway (9) extends through essentially the whole elongate shaft (5).

15. A rectal insertion device as claimed in claim 14, wherein the first passageway (9) has a rearward opening (13) in the rearward portion of the elongate shaft (5).

16. A rectal insertion device as claimed in any one of claims 13 to 15, wherein the rearward portion of the elongate shaft (5) is spaced from the inner wall of the tubular element (3).

17. A rectal insertion device as claimed in claim 16, wherein the elongate shaft (5) is attached to the inner wall of the tubular element (3) through one or more rib elements (6).

18. A rectal insertion device as claimed in any one of the preceding claims, wherein the rearward section (3) comprises a gripping portion (15) for manoeuvring the device.

19. A rectal insertion device as claimed in any one of the preceding claims, wherein the forward section (8) is more flexible than the rearward section (3).

20. A rectal insertion device intended for adults as claimed in any one of the preceding claims, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is at least 30 mm, and preferably in the range 40-50 mm, and most preferably around 45 mm.

21. A rectal insertion device intended for infants as claimed in any one of claims 1 to 19, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is in the range of about 15-35 mm, and preferably in the range 20-30, and most preferably around 25 mm.

22. A rectal insertion device as claimed in any one of the preceding claims, wherein the device further comprises means for collecting faeces discharged into at

least one, and preferably both, of the first and second forward openings.

23. A rectal insertion device as claimed in claim 22, wherein the means for collecting faeces comprises a collection receptacle, and preferably a collection bag.

24. A rectal insertion device as claimed in claim 22, wherein the means for collecting faeces comprises a rearwardly sealed passageway connected to the opening.

25. A rectal insertion device as claimed in any one of the preceding claims, wherein the forward section (8) presents a transversely enlarged forward end portion (12).

26. A rectal insertion device as claimed in any one of the preceding claims, wherein the first passageway (9) is tapering towards the forward end of the forward section (8), making the forward opening the narrowest part of the first passageway (9).

27. A rectal insertion device as claimed in any one of the preceding claims, wherein the rearward section (3) is at least slightly tapering towards a mid-section.

28. A method for treating disorders of the digestive tract of a human or animal patient, comprising the step of at least one time inserting a forward section (8) of a device into the anal canal of the patient, said forward section (8) comprising a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section (8) characterised in that the device is inserted into the anal canal into a position where a rearward section (3) of the device abuts the anus with a forward end, said rearward section (3) comprising a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section.

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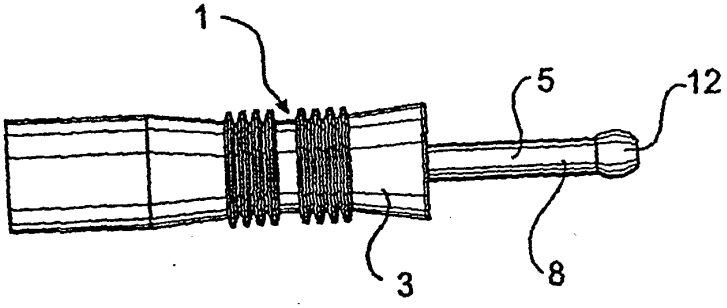
(54) Title: RECTAL INSERTION DEVICE




(57) Abstract: A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient having a body (3, 5) comprises a forward section (8) which in an operative position of the device is disposed in the anal canal of the patient, a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section, a rearward section (3) having a forward end which in the operative position is disposed extra-corporeally and a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section. The second passageway acts to catch faeces discharged from the anal canal not caught in the first passageway.

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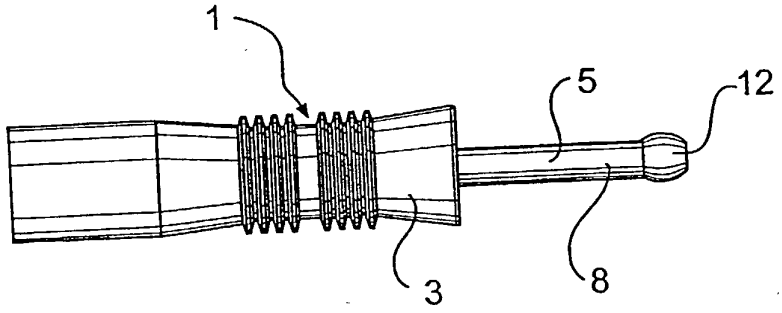


Fig. 1

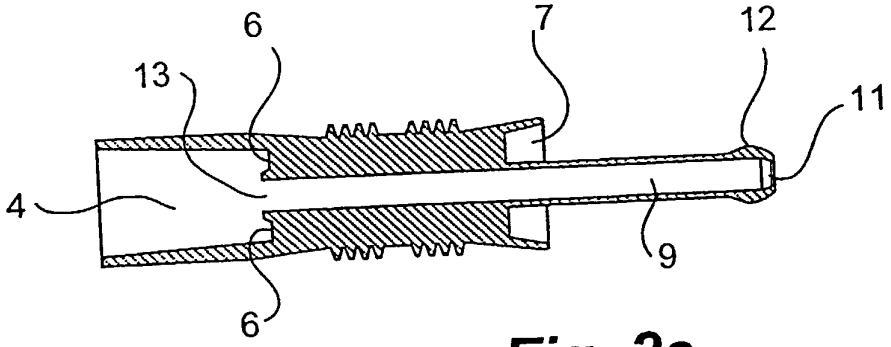


Fig. 2a

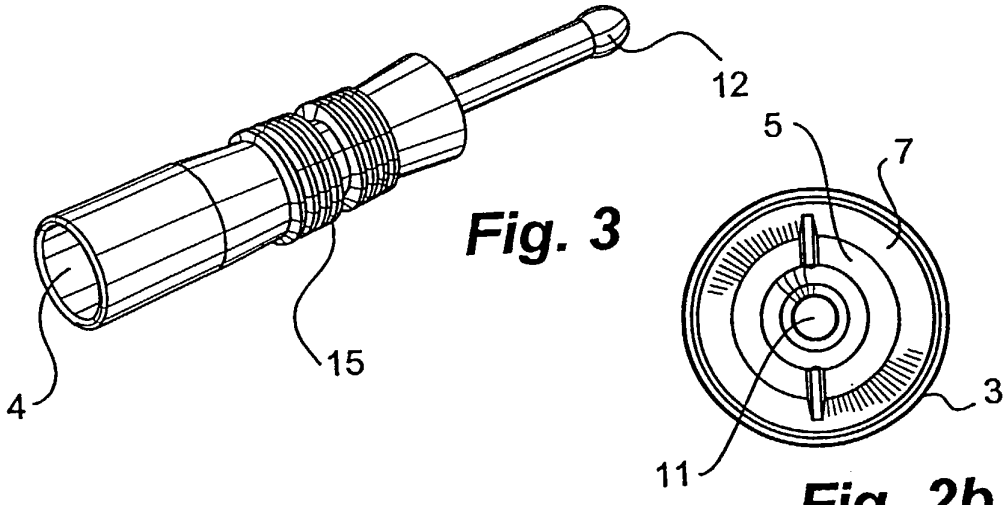


Fig. 3

Fig. 2b

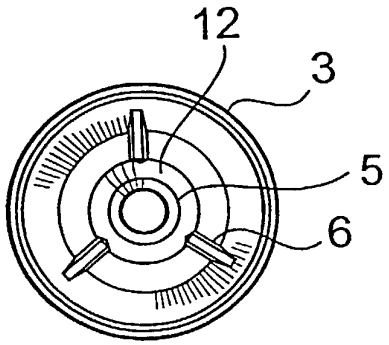


Fig. 5

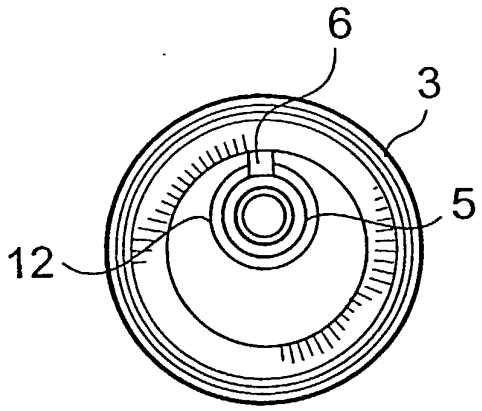


Fig. 6

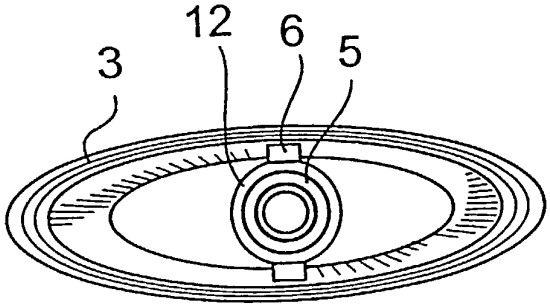


Fig. 7

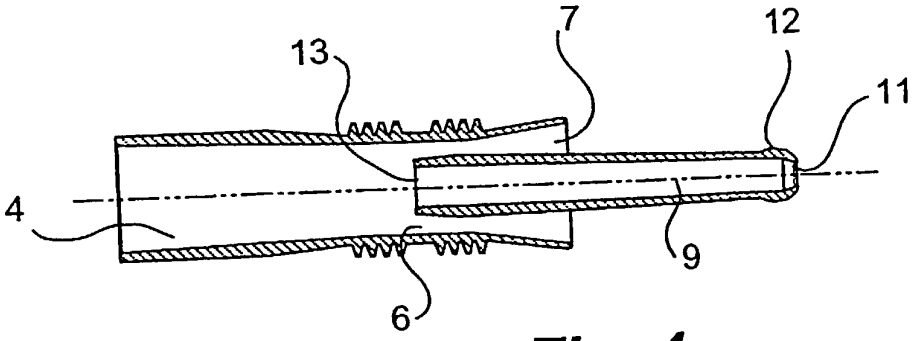


Fig. 4

Attorney Docket No. 0104-0385P

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# COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT AND DESIGN APPLICATIONS

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Insert Title: RECTAL INSERTION DEVICE

Fill in Appropriate Information - For Use Without Specification Attached:

the specification of which is attached hereto. If not attached hereto,
the specification was filed on March 19, 2002 as
United States Application Number ____;
and amended on ____ (if applicable) and/or
the specification was filed on September 28, 2000 as PCT
International Application Number PCT/SE00/01871; and was
amended on ____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representative or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Insert Priority Information: (if appropriate)

| Prior Foreign Application(s) | | | Priority Claimed | |
|---|---|---|---|---|
| 9903613-9 (Number) | SWEDEN (Country) | October 6, 1999 (Month/Day/Year Filed) | ☒ Yes | ☐ No |
| (Number) | (Country) | (Month/Day/Year Filed) | ☐ Yes | ☐ No |
| (Number) | (Country) | (Month/Day/Year Filed) | ☐ Yes | ☐ No |

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional applications(s) listed below.

Insert Provisional Application(s): (if any)

| (Application Number) | (Filing Date) |
|---|---|
| (Application Number) | (Filing Date) |

All Foreign Applications, if any, for any Patent or Inventor's Certificate Filed More than 12 Months (6 Months for Designs) Prior to the Filing Date of This Application:

Insert Requested Information: (if appropriate)

| Country | Application Number | Date of Filing (Month/Day/Year) |
|---|---|---|
| | | |
| | | |

I hereby claim the benefit under Title 35, United States Code, §120 of any United States and/or PCT application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States and/or PCT application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Insert Prior U.S. Application(s): (if any)

| (Application Number) | (Filing Date) | (Status - patented, pending, abandoned) |
|---|---|---|
| (Application Number) | (Filing Date) | (Status - patented, pending, abandoned) |

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Attorney Docket No. 0104-0385P

I hereby appoint the practitioners at **CUSTOMER NO. 2292** as my attorneys or agents to prosecute this application and/or an international application based on this application and to transact all business in the United States Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the practitioners, unless the inventor(s) or assignee provides said practitioners with a written notice to the contrary:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| | | |
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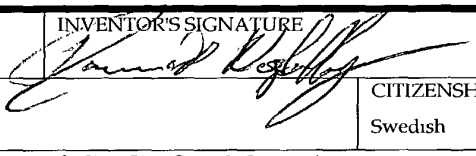
| Full Name of First or Sole Inventor Insert Name of Inventor → Insert Date This Document is Signed | GIVEN NAME/FAMILY NAME<br>Daniel NESTENBORG | INVENTOR'S SIGNATURE<br>  DATE*<br>2002 05 13 |
| Insert Residence Insert Citizenship → | Residence (City, State & Country)<br>Mölndal SWEDEN SE | CITIZENSHIP<br>Swedish |
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| Full Name of Fourth Inventor, if any see above | GIVEN NAME/FAMILY NAME | INVENTOR'S SIGNATURE DATE* |
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| Full Name of Fifth Inventor, if any see above | GIVEN NAME/FAMILY NAME | INVENTOR'S SIGNATURE DATE* |
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